Use of Vaginal Pessaries for Pelvic Organ Prolapse in Chinese Women

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Objective:
To evaluate the efficacy, acceptability, and complications associated with the use of vaginal ring pessaries in the treatment of pelvic organ prolapse in Chinese women.

Study design:
This prospective observational study of patients presenting with symptomatic pelvic organ prolapse was carried out in the gynaecology clinic of a local regional hospital from June to December 2009. Patients were assessed at baseline and 3 months after pessary insertion. Success was defined as a comfortable pessary fitting at the initial visit, with comfort continuing up to the 12-week follow-up visit. Demographic data, symptomatology, pelvic organ prolapse staging, satisfaction score and complications following the use of the pessaries were recorded and subjected to statistical analysis.

Results:
A total of 85 patients were included in the analysis. Their mean age was 66 (standard deviation, 11) years. The 71-mm ring pessary was the most frequently used. Approximately 77% continued with the use of pessary at 3 months. The mean satisfaction score with the use of pessaries was 7.4 (standard deviation, 2.3). There was no association between the pelvic organ prolapse parameters with successful pessary fitting. 77% of the women experienced at least one symptom after pessary use; the most common being vaginal discharge (36.5%) and foul odour (36.5%), each of which occurred in 37% of the patients.

Conclusion:
Vaginal ring pessary is an effective and acceptable first-line treatment option for managing pelvic organ prolapse in Chinese women.

Hong Kong J Gynaecol Obstet Midwifery 2011; 11:40-8

Keywords: Patient satisfaction; Pessaries; Treatment outcome; Uterine prolapse; Vagina

Introduction

Pelvic organ prolapse (POP) is a common gynaecological condition. Although surgery is an effective treatment option, it may not be suitable for all women. Vaginal pessaries are the mainstay of non-surgical treatment for this condition. It was estimated that more than 85% of gynaecologists[1] and almost 98% of urogynaecologists[2] prescribe pessaries in women suffering from POP.

Studies on the use of vaginal pessaries in POP have been reported to improve the prolapse and urinary symptoms in 71-90% and 50% of women, respectively[3,4]. A retrospective study[5] suggested a therapeutic effect on the progression of POP with the use of supporting pessaries. On the other hand, a Cochrane database systematic review[6] in 2004 did not find sufficient evidence of benefit for POP based on randomised controlled trials involving the use of mechanical devices / pessaries. Further studies on the role of vaginal pessaries in the treatment of POP are therefore necessary.

Predictors of unsuccessful pessary fitting include a history of a prior prolapse procedure, previous

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hysterectomy, and increasing parity[4,7]. Severe posterior compartment prolapse was reported to be an important predictor of pessary discontinuation[7,8]. Local hormone replacement therapy has been shown to play an important role in successful pessary fittings[9].

Although vaginal ring pessaries are commonly used in the treatment of POP in Hong Kong, local studies in this area have been sparse. This study was designed to evaluate the efficacy, acceptability, and complications of vaginal ring pessaries for the treatment of POP in Hong Kong Chinese women. Predictors of successful pessary fitting were also investigated.

Methods

This was a prospective observational study carried out from June 2009 to December 2009 in the gynaecology outpatient clinic in a local regional hospital in Hong Kong. The study was approved by the Institutional Review Board of the hospital. All newly referred Chinese women who complained of symptomatic POP and elected to use vaginal pessaries for treatment were included in this study. Women who opted for the use of vaginal pessaries while waiting for operative treatment were also recruited. Exclusion criteria were a history of previous hysterectomy, previous surgery for POP, previous use of a vaginal pessary for POP, and overt clinical features of vaginal infection or ulceration.

All the patients were assessed by the same investigator at each visit. Informed consent was obtained from each patient at the first visit. Patient demographic data, medical and gynaecological histories of POP, and urinary and bowel function were recorded. Prolapse symptoms included: awareness of a lump, mass coming out of the vagina, vaginal soreness, vaginal discharge, dragging pain in the lower abdomen and low back pain. Urinary symptoms included voiding difficulty, urinary urgency, urge incontinence, stress incontinence, and a need for splinting to void. Bowel symptoms assessed included incomplete emptying of the bowel, a need for splinting to defecate, faecal urgency, urge faecal incontinence, rectal digitations to empty the bowel. Sexual activity was also recorded.

In each patient, full physical evaluation — including a pelvic examination — was performed. The Pelvic Organ Prolapse Quantification system (POP-Q) as described by the International Continence Society was used to assess the POP quantitatively[10]. All women were examined in the dorsal lithotomy position with an empty bladder, at rest and with straining during a valsalva manoeuvre. The vaginal pessary option and surgical treatment were discussed with each patient. An appropriate-sized vaginal ring pessary was fitted in patients choosing that treatment option, including those who wanted to use the pessaries while waiting for surgery.

Patients were asked to come back for the second visit 12 weeks later. If the pessary slipped out before the second visit, an appropriate-sized one was reinserted and the patient was reassessed again after 12 weeks. Symptoms related to prolapse, urinary and bowel function were asked about in the same manner as in the first visit. The satisfaction score of the patient was obtained using a dedicated assessment tool. On the numerical rating scale, the women were asked to describe their degrees of satisfaction after the insertion of ring pessaries by choosing a number from 0 (most unsatisfied) to 10 (most satisfied). Side-effects from the use of ring pessaries including pain, slipping, bleeding, discharge, foul odour, pruritus, and difficulty with defecation and voiding were documented. The pessary was removed and the vagina examined for any erosions. The POP-Q examination was repeated in the same manner as in the first visit.

Demographic data, co-morbidities, prolapse, urinary and bowel symptoms, sexual activity, and physical examination findings were summarised using means, medians and percentages. The McNemar test was used to analyse the change of symptoms from baseline to 3 months after pessary insertion. Categorical variables were compared using the Chi-square or Fisher's exact test as appropriate. The Student *t* test was used to compare means. The Wilcoxon signed rank test was used to analyse the POP-Q and prolapse stage measurements at the baseline and 3 months' visits. Successful fitting was defined as a comfortable fitting at the initial visit, which continued up to the 12-week follow-up visit. Persistent inability to retain a pessary or the need for removal due to pain, discomfort or bleeding within 12 weeks was considered an 'unsuccessful fitting' (discontinued use).

Regarding data analysis, a symptom was "improved" if the baseline reply was "yes" and the

3-month reply was "better". A symptom was "persistent" if the baseline reply was "yes" and the 3-month reply was "not better". A symptom was "de novo" if the baseline reply was "no" and the 3-month reply was "yes". For data analysis, patient satisfaction scores were grouped as binary variables, in which "satisfied" was defined as ≥5 and "dissatisfied" as <5.

P values of <0.05 were considered statistically significant. Statistical analysis was carried out using the Statistical Package for the Social Sciences (Windows version 15.0; SPSS Inc, Chicago [IL], USA).

Results

A total of 91 women were referred to the Gynaecology Department because of symptomatic POP during the study period, of whom 85 satisfied the entry criteria and completed the two study visits and to be included in the analysis.

Table 1 shows the demographic and clinical characteristics of the patients. The mean age of the study group was 66 (standard deviation [SD], 11) years. Their mean parity was 3.1 and 88% were postmenopausal. Most subjects (87%) had an active lifestyle with 27% reporting they undertook heavy lifting. The distribution of the POP-Q stages II, III, and IV in the study group consisted of 35%, 49%, and 12%, respectively. In these women, anterior compartment prolapse was the predominant type (67%), whilst apical prolapse occurred in 31% and posterior prolapse occurred in 2%. At the initial assessment, four (5%) of these women intended to have surgery later.

The Figure shows the frequency of distribution of pessary sizes used in the study group. The 71-mm ring pessary was the most frequent (used by 16%). There was no significant difference in the size of ring pessaries in successfully and unsuccessfully fitted patients (p = 0.553).

Table 2 shows the change of general, bladder, bowel, and sexual symptoms of the 85 patients at baseline and 3 months after pessary insertion. The predominant presenting symptoms were awareness of a vaginal lump (96%), the prolapse extruding from the vagina (96%), and dragging pain in the lower abdomen (60%). All these symptoms improved significantly after the use of vaginal pessaries.

Table 1. Demographic and clinical characteristics (n = 85)

Characteristic	Data*
Age (years)	66 ± 11
Duration of symptoms (years)	2.9 (0.5-21.0)
Parity	3.1 (1-7)
Previous vaginal births	3.1 (0-7)
Largest birth weight (kg)	3.4 (2.1-4.3)
Oestrogen status	
Premenopausal	10 (12%)
Postmenopausal	75 (88%)
Oestrogen therapy	0 (0%)
Chronic medical disease	49 (58%)
Lifestyle	
Sedentary	11 (13%)
Active	51 (60%)
Active with heavy lifting	23 (27%)
Chronic cough	79 (93%)
Body mass index (kg/m^2)	24.3 (15.0-34.6)
Sexually active	22 (26%)
POP-Q stage†	
Stage I	3 (4%)
Stage II	30 (35%)
Stage III	42 (49%)
Stage IV	10 (12%)
Predominant compartment	
Anterior	57 (67%)
Apical	26 (31%)
Posterior	2 (2%)
Genital hiatus (cm)	4.13 (2.5-6.0)
Perineal body (cm)	2.68 (1-4)
Total vaginal length (cm)	7.53 (7-9)

* Data are shown as mean ± standard deviation, mean (range), or No. (%)

† POP-Q denotes Pelvic Organ Prolapse Quantification system

Common urinary symptoms at the first visit included: urgency (58%), difficulty in emptying the bladder (54%), stress incontinence (35%), and urge incontinence (33%). All these recorded urinary symptoms improved significantly with the use of vaginal pessaries. On the contrary, de-novo urinary incontinence developed in 6%, and de-novo voiding difficulty developed in 1%.

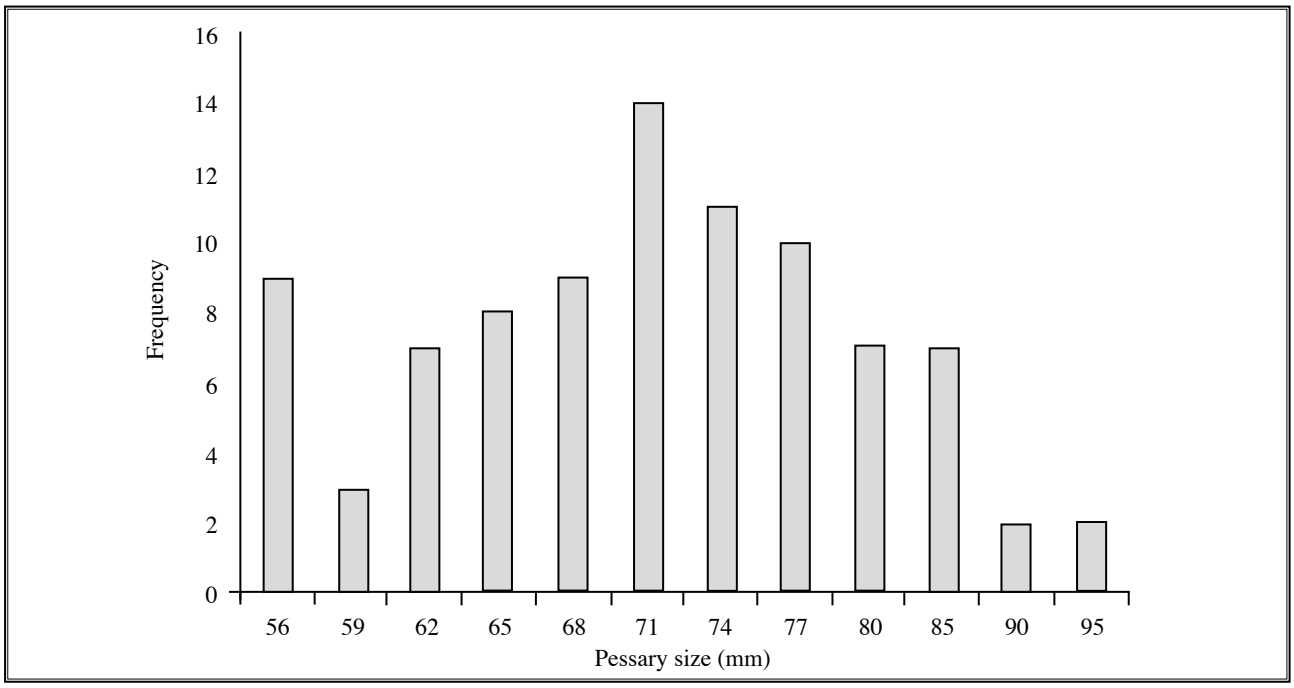

Figure. Frequency of pessary size used

Table 2. Baseline symptoms and change of symptoms 3 months after insertion of vaginal pessaries (n = 85)

Symptom	Symptoms at baseline, No. (%)	Change of symptoms from baseline to 3 months, No. (%)		p Value*
		Improved	Persisting	
General symptoms				
Awareness of a lump	82 (96)	75 (88)	7 (8)	<0.001
Prolapse coming out of vagina	82 (96)	75 (88)	7 (8)	<0.001
Vaginal soreness	16 (19)	3 (4)	13 (15)	0.250
Vaginal discharge	19 (22)	11 (13)	8 (9)	0.001
Dragging pain	51 (60)	44 (52)	7 (8)	<0.001
Low back pain	11 (13)	8 (9)	3 (4)	0.008
Urinary symptoms				
Difficulty in emptying bladder	46 (54)	31 (36)	15 (18)	<0.001
Push prolapse to void	18 (21)	15 (18)	3 (4)	<0.001
Urinary urgency	49 (58)	27 (32)	22 (26)	<0.001
Urge urinary incontinence	28 (33)	16 (19)	12 (14)	<0.001
Stress urinary incontinence	30 (35)	14 (16)	16 (19)	<0.001
Defecatory symptoms				
Incomplete faecal emptying	5 (6)	2 (2)	3 (4)	0.500
Constipations	19 (22)	8 (9)	11 (13)	0.008
Rectal digitations to empty bowel	3 (4)	1 (1)	2 (2)	1.000
Faecal urgency	4 (5)	3 (4)	1 (1)	0.250
Urge faecal incontinence	2 (2)	1 (1)	1 (1)	1.000
Sexual activity				
Improvement in satisfaction	22 (26)	7 (8)	15 (18)	0.016

* p Value from McNemar test

At the baseline visit, 22 (26%) of the women were sexually active, all of whom continued to be sexually active after pessary insertion, 7 (8%) of whom claimed greater sexual satisfaction after its use (p = 0.016).

In all, 65/85 (76%) of the women had continued pessary use at 3 months, whereas 24% had discontinued use. The reasons for discontinuing ring pessaries were repetitive expulsion (45%), discomfort (35%), urinary incontinence (10%), and slowed urine stream (5%). One woman (5%) discontinued using the pessary because it was too time-consuming to attend the clinic regularly to change it (Table 3). Among those who had discontinued pessary use at 3 months, 35% decided to undergo surgical treatment of genital prolapse, while 65% elected to receive expectant management only.

Table 3. Reasons of discontinued use of pessary (n = 20)

	No. (%) of patients
Slipping	9 (45)
Discomfort	7 (35)
Urinary incontinence	2 (10)
Slower urine stream	1 (5)
Time-consuming	1 (5)

There was no significant difference in the age, parity, menopausal status, sexual activity status, and body mass index of the women who were successfully and unsuccessfully fitted with a pessary. Women who continued using vaginal pessaries had a shorter duration of symptoms than the rest (2.2 years vs 5.2 years; p = 0.003).

Table 4 shows the relationship between the various characteristics of the prolapse and the outcomes of pessary use. There was no association between successful pessary fitting and stage of the prolapse, or the predominant compartment involved. Nor was there any significant difference between successfully and unsuccessfully treated patients, with respect to the genital hiatus, perineal body, and total vaginal length measurements.

At follow-up, 35 women (41%) showed improvement in the POP stage and none experienced any worsening (Table 5). At 3 months, the mean satisfaction score of these patients was 7.4 (SD, 2.3); 66 (78%) were satisfied with their pessaries and enjoyed subjective overall symptomatic improvement. While 77% of them experienced at least one symptom including vaginal discharge (37%), slipping (25%), discomfort (19%) or erosion (11%), none suffered severe complications (Table 6).

Table 4. Relationship between successful pessary trial and prolapse characteristics*

	Continued use (n=65)	Discontinued use (n=20)	p Value†
POP-Q stage‡			0.506
I	0 (0)	3 (4)	
II	24 (28)	6 (7)	
III	35 (41)	7 (8)	
IV	6 (7)	4 (5)	
Predominant compartment			0.343
Anterior	50 (59)	7 (8)	
Apical	15 (18)	11 (13)	
Posterior	0 (0)	2 (2)	
Genital hiatus (cm)	4.12 ± 0.90	4.18 ± 0.88	0.794
Perineal body (cm)	2.65 ± 0.58	2.80 ± 0.50	0.286
Total vaginal length (cm)	7.5 1 ± 0.56	7.60 ± 0.13	0.529

* Data are shown as mean ± standard deviation or No. (%)

† p Value from Chi-square, Student *t* test

‡ POP-Q denotes Pelvic Organ Prolapse Quantification system

Table 5. Comparison between the stage of pelvic organ prolapse at baseline and after 3 months of pessary use

Initial stage	Stage after 3 months*				
	I	II	III	IV	Total
I	3	0	0	0	3 (4%)
II	8	22	0	0	30 (35%)
III	0	23	19	0	42 (49%)
IV	0	0	4	6	10 (12%)
Total (%)	**11 (13%)**	**45 (53%)**	**23 (27%)**	**6 (7%)**	**85 (100%)**

* $p < 0.001$ (Wilcoxon signed rank test)

Table 6. Complications arising from using a ring pessary (n = 85)

Complication	No. (%) of patients
Yes	65 (77)
Discomfort	16 (19)
Bleeding	6 (7)
Slipping	21 (25)
Foul odour	31 (37)
Vaginal discharge	31 (37)
Itchy sense	7 (8)
Erosion	9 (11)
Slower urine stream	3 (4)
Urinary incontinence	8 (9)
Difficulty with defaecation	1 (1)
No complication	20 (24)

Discussion

In our prospective observational study of 85 women with symptomatic POP, 65 patients (77%) continued pessary use at 3 months. Five other studies evaluating fitting of pessaries showed successful fitting rates ranging from 56% to 75%[4,5,11-13], which were similar to our success rate.

Clemons et al[11] performed a prospective study on 100 women with symptomatic POP and reported a success rate of 73% at 2 months. They found that a short vaginal length and a wide introitus were risk factors for an unsuccessful pessary fitting. However, our data did not show any relationship between the genital hiatus, perineal body and total vaginal length, and pessary fitting outcome.

Similar to the studies by Fernando et al[4], Clemons et al[11] and Mutone et al[14], we did not find any significant difference in age, degree (assessed by POP-Q system), and predominant site of the POP between those who had successful and failed fittings. Although Fernando et al[4] reported that increasing parity was a risk factor associated with pessary failure, no such correlation was noted by Clemons et al[11], Brincat et al[15], or in our study. Brincat et al[15] suggested that sexual activity predicts continued pessary use, while no such correlation was found by Clemons et al[11] or in our study. Mutone et al[14] suggested that obesity was associated with a significantly lower likelihood of successful pessary use, but no such relationship was noted by us.

It has been reported that 40-50% of patients with severe POP also suffer detrusor overactivity[16,17], and the likelihood of detrusor overactivity resolving after corrective surgery for POP was between 33% and 50%[18]. The significant improvement in urgency and urge incontinence after pessary insertion in our patients might be due to rectification of secondary detrusor overactivity related to POP[16,17]. POP is associated with anatomical distortion of the urethra, which may result in voiding difficulties[19]. In our study, 46 (54%) of the patients presented with difficulty in emptying their bladder. However, in 31 of them this symptom improved after pessary use, probably due to restoration of bladder and urethra anatomy.

The frequency of bowel symptoms reported in POP in the studies by Fernando et al[4] and Kapoor et al[20] were 78% and 62%, respectively. Our study encountered a lower frequency, nor was there any significant improvement in the corresponding symptoms after pessary use. The latter was probably related to the low baseline frequency of such

symptoms and a relatively small proportion (2%) of predominantly posterior compartment prolapse in our patients.

POP is perceived to affect sexual function[21-23]. Impairment of sexual function and increasing durations of abstinence were strongly associated with worsening POP[24,25]. Fernando et al[4] reported that there was a significant improvement in sexual function 4 months after pessary use. Kuhn et al[26] also reported that desire, lubrication and sexual function improved significantly by 3 months after pessary use. In our study, 22 (26%) of the patients were sexually active, 7 of whom reported improvement in sexual satisfaction after pessary use ($p = 0.016$). Desire and satisfaction might be influenced by the improvement in general well-being, which might alter patient self-esteem. During our study, many women expressed concern that the vaginal pessary might interfere with sexual activity. Our findings were encouraging in this respect, and should be used to counsel women on sexual functioning, if they are contemplating using a vaginal pessary.

Sarma et al[27] evaluated the prevalence of adverse events associated with vaginal ring pessary use at a minimum of 6 years in 273 women. 56% experienced complications comprising: bleeding, extrusion, vaginal discharge, pain and constipation. After cessation, 44% chose conservative treatment and 30% opted for surgery. Bai et al[28] reported that 73% of women experienced at least one symptom including bleeding (19%), vaginal discharge (17%), slipping (15%) and discomfort (10%) after pessary use; 19% of them stopped using the pessary due to slipping (55%), discomfort (25%) and inflammation (20%).

In our study, 77% of the women experienced at least one complication from the use of vaginal pessaries within the 3-month follow-up. The commonest complaints were vaginal discharge (37%) and foul odour (37%). A study comparing pessary users with non-users found that the presence of foreign body increased the risk of bacterial vaginosis by 4-fold[29]. In most cases, the symptoms were short-lasting[30]. Symptomatic women with bacterial vaginosis can be treated empirically without vaginal culture.

Fitting of pessaries is a trial-and-error process with a goal of fitting the largest possible device that does not cause discomfort. The average number of ring pessary insertion attempts per person was 1.5. One woman felt that there was shifting of the pessary during walking, which was solved by increasing its size. Slow urine stream and difficulty with defaecation could be resolved by decreasing the pessary size. The most common reasons for discontinuation were repetitive expulsions (45%) and discomfort (35%). Some researchers attempt using two ring pessaries of different size in order to avoid repetitive slipping[31]; the top ring being smaller and lighter than the lower one. By this means, the lower ring provides support at a different level of the vagina. Double rings were used in one of our patients, but were later expelled. Later, she underwent vaginal hysterectomy.

Vaginal erosions occurred in 11% of our study group. When ulcerations occurred, the pessary could be removed to allow the ulcers healing. The women were advised to use intravaginal oestrogen cream for 3 weeks, after which the pessaries could be replaced when the lesions had healed. More serious complications have been reported from neglected pessary use. These include: incarceration or perforation of the cervix, small bowel prolapse and incarceration, peritonitis, vesicovaginal fistula, hydronephrosis, vaginal cancer, erosion into the bowel or bladder, and dense adherence to other pelvic structures[32-35]. It is important to explain all these possible problems to the patients and the need for follow-up should be emphasised, though there is no consensus on how frequently a patient should be seen after a pessary is fitted successfully[36]. Some authors[12,29] suggest that they should be seen every 3 months in the first year, and every 6 months thereafter. We adopted a similar follow-up schedule in our clinic.

Several authors have studied satisfaction with the use of vaginal pessaries. Sitavarin et al[37] evaluated 40 patients, of whom 93% were satisfied and continued to use their pessaries. Clemons et al[3] assessed patient satisfaction after 2 months of pessary use; 92% of the women with a successful pessary fitting trial were satisfied. Bai et al[28] reported that 70% of the women answered that they were satisfied or more than satisfied. With the use of pessaries for the management of POP, the mean patient satisfaction score in our study was 7.4 ± 2.3. 78% were satisfied with their pessaries

and they reported subjective improvement in overall symptoms.

Our study was limited by the relatively small sample size and lack of a control group. Treatment outcomes were assessed and reported after 3 months, though longer follow-up of a larger sample might have more information. Patient symptoms were asked about directly by the investigator, but in future a validated questionnaire on POP should be considered. Large prospective randomised studies with long-term follow-up are necessary to assess the effects of pessaries on the progression of POP.

To the best of our knowledge, our study was the first prospective study on the use of vaginal pessaries in POP in our locality, which provides a simple, inexpensive and non-invasive treatment option. In our study, it was shown to be effective in improving prolapse-associated symptoms, and in stabilising the prolapse stage. The vaginal pessary was acceptable to most of our patients. Complications were relatively minor and easily correctable. The frequency of pessary removal was low. Our findings suggested that the vaginal pessary is an acceptable first-line option in the treatment of POP and the patients awaiting surgery.

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